

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

**IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION**

**MDL NO. 1968**

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**THIS DOCUMENT RELATES TO ALL CASES**

**DEFENDANT ACTAVIS TOTOWA LLC'S RESPONSE TO THE COURT'S  
SEPTEMBER 8, 2011 ORDER (DOC. 575)**

**I. INTRODUCTION**

Defendant Actavis Totowa LLC ("Actavis") respectfully requests that this Court bar any use of Plaintiffs' Exhibit 217 at the *Daubert* and Motions Hearing set for September 14, 2011, which would moot the redaction issue. At a minimum, Actavis requests that the Court permit its requested redactions. (*See* proposed redactions at Exhibit 1 to Doc. 566).

Plaintiffs' Exhibit 217 was inadvertently produced without redacting non-Digitek® information that this Court already held is irrelevant and not discoverable in Pretrial Orders #s 12, 27 and 37. Plaintiffs have not shown that the information at issue "is reasonably related to Digitek®" under these Orders, and therefore discoverable. As a result, Plaintiffs have no right to use this Exhibit at the September 14 Hearing. And allowing them to selectively introduce information about unrelated out-of-specification investigations would be highly prejudicial

**II. PROCEDURAL HISTORY**

This Court has already ruled – over two years ago and after extensive briefing by all parties – that the non-Digitek® information in Exhibit 217 is not discoverable. (*See* Docs. 71, 150, and 185). In its September 8, 2011 opinion, the Court correctly noted that under PTO #12 Actavis may redact from produced documents "[a]ny information relating to products other than

Digitek®, unless manufacturing information about a product other than Digitek is *reasonably related to Digitek manufacturing*.” (Doc. 575 citing Doc. 71 at 5, ¶ IIF(4)) (emphasis added). The Court then broadly stated, however, that “[s]ome of plaintiffs’ arguments center on the manufacturing processes of defendant Actavis. The information the defendants’ propose to redact appears to be relevant to that issue.” (Doc. 575 at 2). This statement is at odds with the Court’s prior Orders and was prompted by Plaintiffs’ counsel’s misrepresentations and failure to be candid with the Court. The only basis for this statement is the affidavit of Terry Kikpatrick, counsel for the plaintiff, that there is “probative information” in the document and that “there are numerous issues concerning blend uniformity, compression, and tablets out of specification with regard to thickness of non-Digitek products that bear directly on the issues presented in this litigation.” (See Doc. 567 at 3-4). This document does not meet the terms of discoverability set out by this Court. Plaintiffs’ counsel failed to advise the court of the key facts relating to this document in relationship to those court-established standards.

After PTO #12, the Court interpreted “reasonably related to Digitek manufacturing” to significantly restrict Plaintiffs’ non-Digitek® document discovery. (See PTO #27 - Doc. 150 and PTO #37 – Doc. 185). The parties have operated under these Orders for over two years. In these Orders, the Court rejected Plaintiffs’ request to expand discovery to all products manufactured at Actavis’ Little Falls plant, which is exactly the type of information at issue here.<sup>1</sup> *Id.* The Court found the relevance of such information to be “too speculative” and considered the request an “overbroad and expensive fishing expedition.” (Doc. 185 at 6). It then carved out a narrow exception and allowed discovery only of non-Digitek® batch records for batches that: (1) were manufactured immediately before a recalled Digitek® batch; and (2) used

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<sup>1</sup> In PTO # 59, the Court permitted Plaintiffs to ask additional questions at deposition regarding non-Digitek® information. (Doc. 330 at 7-12). But did not change its prior orders limiting non-Digitek® document discovery. *Id.* Plaintiffs did not subsequently question any witnesses regarding Exhibit 217.

the same equipment as Digitek®. (Doc. 150 at 15-17; Doc. 185 at 6-7). The Court explained that “it is the court’s intention that [a] plaintiff should be able to trace backwards the lot number of his prescription to the manufacture of those tablets, and to determine the likelihood that Digitek® contained only the ingredients it was supposed to contain, in the specified amounts.” (Doc. 150 at 16; Doc 185 at 2). Plaintiffs’ Exhibit 217 does not fit this specific exception and is therefore not discoverable.

### **III. PLAINTIFFS’ EXHIBIT 217 HAS NO RELEVANT INFORMATION AND IS HIGHLY PREJUDICIAL.**

Plaintiffs oppose Actavis’s redactions, but have not shown that the non-Digitek® information in Exhibit 217 fits the Court’s narrow criteria for discoverability laid out in PTO #s 27 and 37.<sup>2</sup> Nor can they. Plaintiffs’ last second, generic claim that this document touches on blend uniformity, compression and out-of-specification tablet issues is wholly insufficient under PTO #s 12, 27 and 37. (Doc. 567 at 2-4). Moreover, allowing Plaintiffs to cherry pick this irrelevant information completely out of context is highly prejudicial.

Exhibit 217 generally summarizes all out-of-specification investigations performed at Little Falls for a given time period. There is no proof or testimony that the non-Digitek® batches on this document: (1) were manufactured immediately before a Digitek® batch (let alone the specific batches Plaintiffs allegedly ingested); and (2) used the same equipment as a Digitek® batch. There is also no proof or testimony linking any out-of-specification Digitek® with any of these non-Digitek® investigations. Exhibit 217 was not part of Actavis’ subsequent

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<sup>2</sup> Plaintiff’s response briefs to Defendants’ various motions were due on August 24, 2011. On that day at 12:23 p.m. eastern, Plaintiff’s counsel, for the first time, asked Defendants to consider changing the confidential designation for a significant number of documents, including Ex. 217. See Exhibit A to Matt Moriarty’s Affidavit attached hereto as Exhibit 1 and ¶¶4-6. Plaintiffs also called Matt Moriarty that day, but did not tell him what exhibits they intended to file; only that they were thousands of pages. Moriarty Aff. at ¶2. Nor did Plaintiffs send Defendants a list of the exhibits to consider. Id. at ¶6. This is wholly insufficient to comply with Article V of PTO #12, which says that any party wishing to use confidential information at a hearing or trial – “must provide reasonable notice to the Supplying Party of the intended use of [the material].” (Doc. 71 at 9, ¶V(A)).

production of the selected non-Digitek® batch records made pursuant to PTOs 27 and 37, it was produced because Digitek®-related information appears in the document. Plaintiffs' counsel has failed to advise the court of this key fact—this document does not meet the standard for non-Digitek® documents that are relevant. As a result, the non-Digitek® information was not discoverable in the first place and Plaintiffs have no right to use it in this context.

Nor have Plaintiffs used it in that manner thus far. Plaintiffs only cite to Exhibit 217 in their responses to Defendants' dispositive motions for the Digitek®-specific information Actavis does not seek to redact. (Doc. 549 at 4; Doc. 550 at 4). Indeed, Plaintiffs made no effort during discovery to examine the non-Digitek® information or attempt to link it with Digitek® in any way. At deposition, they asked only about the Digitek® information. (Sherwani Dep. at 107:7-117:3 and 209:14-212:7, attached as Exhibit 2). It was not until the redaction issue arose that Plaintiffs suddenly claimed a need to use this irrelevant information.

Moreover, Plaintiffs' superficial claim that the non-Digitek® information in Exhibit 217 is relevant because it concerns "blend uniformity, compression and tablet width" is wholly insufficient and is simply incorrect. It is one thing to say Plaintiffs may *discover* this information; it is entirely another matter to allow this document—by itself—to be used at the September 14, 2011 hearing on dispositive motions (or at trial) to form even some part of the basis for Plaintiffs satisfying their burden of proof on the issue of product defect. The time to establish a link between the non-Digitek® information in Exhibit 217 and defective Digitek® was *during* discovery; not by a last second, self-serving affidavit from Plaintiffs' counsel.

Not only is this information irrelevant and not discoverable, it is highly prejudicial. Per this Court's Orders, no other documents regarding these non-Digitek® investigations were produced. Plaintiffs propose to take Exhibit 217 completely out of context to highlight, in a

cursory fashion, a few out-of-specification results encountered during production of thousands of non-Digitek® batches.<sup>3</sup> Plaintiffs want to cherry pick this irrelevant and highly prejudicial information without any demonstrated connection to Digitek® to further distract from the real issues in this case and to support yet another “inferential leap” from some general, non-Digitek® manufacturing issue to the unsupported conclusion that defective Digitek® was produced and released. The parties should be narrowing the issues at this point, not reopening old discovery disputes settled long ago.

#### IV. CONCLUSION

Defendant Actavis Totowa LLC respectfully requests, in accordance with Pretrial Orders 12, 27, and 37, that this Court bar Plaintiffs from using Exhibit 217 at the September 14, 2011 *Daubert* and Motions Hearing. At a minimum, Actavis requests that this Court permit the partial redaction of the irrelevant and prejudicial information found in Plaintiffs’ Exhibit 217.

Respectfully submitted,

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<sup>3</sup> Ignoring their lack of relevancy to this litigation, these investigations are required and entirely appropriate (21 CFR 211.192), and do not indicate negligence in and of themselves. But Actavis is severely hampered from proving this at such a late date, because the related documents were not produced per this Court’s Orders.

**CERTIFICATE OF SERVICE**

I hereby certify that on September 12, 2011, a copy of the foregoing **DEFENDANT ACTAVIS TOTOWA LLC'S RESPONSE TO THE COURT'S SEPTEMBER 8, 2011 ORDER (DOC. 575)** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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